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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,131	06/22/2000	WOLFGANG ROHDE	147-193P	1520

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/22/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,131	ROHDE ET AL.	
	Examiner	Art Unit	
	Diana Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> . |

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DETAILED ACTION

1. The instant application is the national phase of PCT/EP98/04877, filed August 5, 1998. It is noted that the examiner has considered the International Search Report and International Preliminary Examination Report for PCT/EP98/04877.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-11, in Paper No. 14 is acknowledged. The traversal is on the following ground(s). First, the response argues that the Rohde reference is not anticipatory, stating that "Rodhe [sic] only describes primers roughly by their ability to bind to the sequence of Copia-like elements" and that "No single primer is described in the publication by" its sequence. Second, the response argues that "the Examiner has not properly construed or applied the unity of invention standard applicable under PCT Rule 13, as is clear from a review of the international phase of this application." The response argues that no lack of unity was found in the international application and that "the U.S. application must be examined for Unity of Invention consistent with the" PCT, referring to *Caterpillar Tractor Co. v Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. VA1986).

Applicant's arguments have been thoroughly considered but are not persuasive. First, with respect to applicant's argument that the Rohde reference is not anticipatory, it is noted that Rohde does in fact anticipate the claimed invention. The claimed invention does not require the use of, e.g., particular primer sequences that are not disclosed by Rohde. See the rejection set forth in paragraph 11, below. Second, it is noted that unity of invention is assessed at each phase of the examination of an application.

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Further, the unity of invention standard was applied in the restriction of the instant application, and reasons for a finding of lack of unity given, in paper no. 13. The claimed invention does not make a contribution over the art, and unity of invention is lacking, for the reasons discussed in paper no. 13. Accordingly, in the instant case the examiner did not make "mere reference to the PCT Rule;" nor did the examiner require compliance with any requirements different from or in addition to those provided for in the Patent Cooperation Treaty or Regulations, as was the case in *Caterpillar*. Rather, the proper standard for assessing unity in both an international application and in a 371 application was applied in the instant application. Accordingly, applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Drawings

4. It is noted that the formal drawings have been approved by the draftsperson.

Specification

5. The disclosure is objected to because of the following informalities.
- a) The disclosure does not include the section headings required by 37 C.F.R. 1.77. See MPEP 608.01(a). Appropriate correction is required.

b) The description of Figure 10 does not provide a description of Figure 10B or Figure 10C. While it is not longer necessary to make separate reference to each of 10A, 10B, and 10C in the description, a brief description of the figures of 10B and 10C is still required (i.e., the description of Figure 10 should include a description of the entire figure, including the figures of 10B and 10C). See MPEP 608.01(f).

Claim Objections

6. Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 6 as written depends both from claim 5 and from "any one of the preceding claims."

Claim Rejections - 35 USC § 112

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 provide for the use of a primer or primer pair, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. With further respect to claim 11, it is noted that this claim recites a number of possible uses for another previously recited use, without providing any method steps. Accordingly, claim 11 is further indefinite for failing to recite any steps delimiting how the

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further recited uses are actually practiced. Claim 11 also must be amended to clarify how "fingerprint analysis" is to be employed in the practice of other methods.

Regarding claims 1-11, the phrases "for example," "e.g.," "in particular," "preferably," "most preferably," and "such as, for example," which occur throughout the claims, render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 1-11 are indefinite over the recitation of the phrase "characterized in that." It is unclear as to whether the language following this recitation refers to actual, active method steps, or whether the claims might encompass mental steps of "characterizing" a use or method.

Claims 1-11 are indefinite over the recitation of the terms "obtainable" and "derivable." It is unclear as to whether these terms refer to actual active steps of "obtaining" or "deriving," or whether the claims might encompass, e.g., theoretical steps or manipulations. The claims should be amended to set forth actual, active method steps.

Claims 3-6 are indefinite over the recitation of the limitation "the DNAs to be analyzed" in claim 3. There is insufficient antecedent basis for this limitation in the claims.

Claims 5-6 are indefinite over the recitation of the limitation "the DNAs transferred onto a membrane" in claim 5. There is insufficient antecedent basis for this limitation in the claims.

Claims 9-10 are indefinite because it is unclear as to how the claims may be intended to further limit claim 1 to the extent that claim 1 is drawn to methods in which a "primer pair" is employed. Claims 9-10 recite a further requirement for "the primer." As claim 1 recites a "primer or primer pair," it is unclear whether claim 9-10 would further embodiments of claim 1 requiring a "primer pair," etc. Clarification is required.

Claims 9-10 are indefinite over the recitation of the phrases "the sequences as represented in Table 2" in claim 9 and "the sequences represented in table 1 or 2" in claim 10. There is insufficient antecedent basis for these recitations in the claims, and it is unclear as to what structural and functional properties would actually be required of a primer in order for it to meet the requirement of being a sequence "represented in" Table 1/table 1 or table 2. The claims should be amended so as to provide a clear description of the primers encompassed by the claims.

Claim 9 is indefinite over the recitation of the language "primer displays" a sequence. It is unclear as to what is meant by this language, and as to whether applicant's intent is to actually require a primer that shows or "displays" a sequence in some manner, or whether the claim is intended to encompass a primer comprising a particular nucleic acid sequence, etc.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rohde (Journal of Genetics & Breeding 50:249-261 [9/1996]).

The instant claims are drawn to a use of primer or primer pair in DNA fingerprint analysis. The claims require a primer or primer pair with which a fingerprint is "obtainable from humans as well as from animals as well as from plants as well as from microorganisms" wherein the primer or primer pair will "hybridize to a DNA which codes the endonuclease, the reverse transcriptase or the RNase H of a copia or copia-like element, in particular of coconut (*Cocos nucifera* L.)." It is noted that the instant claims encompass fingerprinting using any type of conditions, and that it is an inherent property of any primer or primer pair that it may be employed successfully in "fingerprint analysis" of any target molecule given appropriate reaction conditions. Further, it is noted that the claims encompass primers that "hybridize" to the recited target copia sequences under any conditions, and that it is an inherent property of any primer or primer pair that it would hybridize to the required target under sufficiently permissive conditions.

Rohde teaches a method of DNA fingerprinting analysis termed inverse sequence-tagged repeat (ISTR) analysis (p. 250). In ISTR analysis, primers "derived from coconut *copia*-like sequences amplify homo- and polymorphic DNA segments in the analysis of plant, animal and human genomes" (p. 250). Accordingly, Rohde discloses a use meeting the requirements of the claims. With respect to claims 3-4, Rohde's fingerprinting method results in the production of multiple PCR products which are displayed on sequencing gels (Figs. 2-4, 6-8). With respect to claims 7-8, Rohde discloses the use of digoxigenin labeled primers and radioactive primers (p. 250). With respect to claims 9-10, Rohde teaches "coconut *copia* sequence-derived" PCR primers ISTR-F1, ISTR-F2, ISTR-F3, ISTR-F5, ISTR-F6, ISTR-F7, ISTR-B1, ISTR-B2, ISTR-B3, ISTR-B4, and ISTR-B5 (Figure 1), corresponding to several of the primers "represented" in Table 1 (see p. 15 of the specification, as well as Figure 2) and overlapping sequences of both table 1 and table 2. With respect to claim 11, Rohde's analyses constitute studies of, e.g., biodiversity and genetic relationships.

12. Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Welsh et al (Nucleic Acids Res. 18(24):7213-7218 [12/1990]).

Welsh et al disclose a method of DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers (see entire reference). Welsh et al disclose that their method "can be applied to any species for which DNA can be prepared" (p. 7213). It is an inherent property of the arbitrary primers of Welsh et al that they would hybridize to the *copia* sequences of the claims under sufficiently permissive conditions. Accordingly, Welsh et al anticipate the instant claims. With respect to claims 3-4, Welsh

et al's fingerprinting method results in the production of multiple PCR products which are displayed on sequencing gels (see, e.g., Figs. 2-4). With respect to claim 10, it is an inherent property of the primers taught by Welsh et al that they overlap "sequences represented in table 1 or 2." With respect to claim 11, Welsh et al's analyses constitute studies of, e.g., biodiversity and genetic relationships.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (Journal of Genetics & Breeding 50:249-261 [9/1996]) in view of Newton (PCR Essential Data, John Wiley & Sons, 1995, p. 104-107).

Rohde teaches a method of DNA fingerprinting analysis termed inverse sequence-tagged repeat (ISTR) analysis (p. 250). In ISTR analysis, primers "derived from coconut *copia*-like sequences amplify homo- and polymorphic DNA segments in the analysis of plant, animal and human genomes" (p. 250). Rohde's fingerprinting method results in the production of multiple PCR products which are displayed on sequencing gels (Figs. 2-4, 6-8). However, Rohde does not teach Southern blotting of such PCR products with labeled probes, as required by claim 5. Regarding "Membrane detection of PCR products", Newton teaches that "Immobilization of DNA on to a solid

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support followed by hybridization to at least one internal probe enhances the sensitivity and characterization of specific product detection compared to gel electrophoresis" (p. 104-5). In view of the teachings of Newton, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rohde so as to have included a step of Southern blotting and hybridization of amplification products with a labeled probe. An ordinary artisan would have been motivated to have made such a modification for the advantage of enhanced sensitivity of detection, as suggested by Newton.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde in view of Newton, as applied to claim 5, above, and further in view of Bell et al (US Patent No. 5,541,060 [6/1996]).

The combined references of Rohde and Newton suggest the use of an internal probe, and the references do not teach a method in which "the probe is the primer or the primer pair" employed in amplification, as recited in claim 6. Bell et al disclose the use of a labeled amplification primer in detection of amplification products that have been separated on a polyacrylamide sequencing gel and blotted to a membrane (see Table 1). In view of the teachings of Bell et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rohde in view of Newton so as to have substituted a labeled amplification primer, as taught by Bell et al, for the internal probe disclosed by Newton. It would have been obvious to one of ordinary skill in the art at the time the invention was made that this modification would allow one to detect amplification products in a more sensitive

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manner while obviating the need to prepare the separate, internal probe disclosed by Newton. Accordingly, an ordinary artisan would have been motivated to have made such a modification for the advantages of increased efficiency and convenience in detecting amplification products.

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Welsh et al (Nucleic Acids Res. 18(24):7213-7218 [12/1990]) in view of Newton.

Welsh et al disclose a method of DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers (see entire reference). Welsh et al disclose that their method "can be applied to any species for which DNA can be prepared" (p. 7213). It is a property of the arbitrary primers of Welsh et al that they would hybridize to the copia sequences of the claims under sufficiently permissive conditions. However, Welsh et al not teach Southern blotting of their PCR products with labeled probes, as required by claim 5. Regarding "Membrane detection of PCR products", Newton teaches that "Immobilization of DNA on to a solid support followed by hybridization to at least one internal probe enhances the sensitivity and characterization of specific product detection compared to gel electrophoresis" (p. 104-5). In view of the teachings of Newton, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Welsh et al so as to have included a step of Southern blotting and hybridization of amplification products with a labeled probe. An ordinary artisan would have been motivated to have made such a modification for the advantage of enhanced sensitivity of detection, as suggested by Newton.

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17. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Welsh et al in view of Newton, as applied to claim 5, above, and further in view of Bell et al.

The combined references of Welsh et al and Newton suggest the use of an internal probe, and the references do not teach a method in which "the probe is the primer or the primer pair" employed in amplification, as recited in claim 6. Bell et al disclose the use of a labeled amplification primer in detection of amplification products that have been separated on a polyacrylamide sequencing gel and blotted to a membrane (see Table 1). In view of the teachings of Bell et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Welsh et al in view of Newton so as to have substituted a labeled amplification primer, as taught by Bell et al, for the internal probe disclosed by Newton. It would have been obvious to one of ordinary skill in the art at the time the invention was made that this modification would allow one to detect amplification products in a more sensitive manner while obviating the need to prepare the separate, internal probe disclosed by Newton. Accordingly, an ordinary artisan would have been motivated to have made such a modification for the advantages of increased efficiency and convenience in detecting amplification products.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

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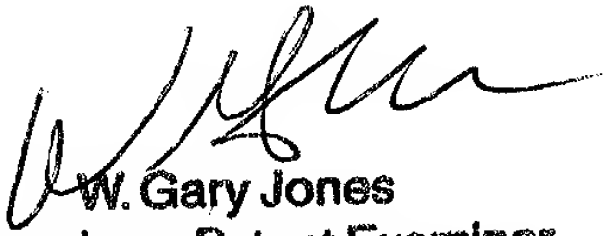
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
May 20, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600